IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Atty. Docket: EIS-SCHWARTZ=2A

In re Application of: Michal Eisenbach-Schwartz

Conf. No.: 1155

Appln. No.: 09/893,348

Art Unit: 1647

Filed: June 28, 2001

Examiner: Bridget Bunner

For: ACTIVATED T-CELLS, NERVOUS SYSTEM-SPECIFIC ANTIGENS AND THEIR USES

Washington, D.C.

November 4, 2002

RESPONSE

Honorable Commissioner for Patents
Washington, D.C. 20231

Sir:

The present communication is responsive to the Office Action of October 2, 2002. Claims 1-44 presently appear in this case. No claims have yet been examined on the merits. All of the claims have been subject to restriction and election requirements. Reconsideration and withdrawal of the restriction requirement, and examination and allowance of all the claims now present in the case are hereby respectfully urged.

The examiner has required restriction among the following Groups of allegedly independent instinct inventions. Groups I-VI are drawn to methods for promoting nerve regeneration or conferring neuroprotection, and Groups VII to

XII are drawn to methods for preventing or inhibiting neuronal degeneration. Group XIII is drawn to a method for preventing or inhibiting neuronal degeneration by administering a composition for up-regulating B7.2 co-stimulatory molecule or genetically manipulating B7.2 co-stimulatory molecule. Within Groups I to VI and Groups VII to XII, the examiner considers each of the administration of (a) NS-specific activated T-cells, (b) NS-specific antigen or analogue, (c) peptide derived from an NS-specific antigen, (d) a nucleotide sequence encoding an NS-specific antigen, (e) a nucleotide sequence encoding a peptide derived from an NS-specific antigen, and (f) any combination of (a)-(e) as being independent and distinct aspects of the method. The examiner considers the methods to be patentably distinct because they require different ingredients, process steps, and endpoints. This rejection is respectfully traversed, at least as so far as Groups I to XII are concerned.

Claim 1 is a generic claim that is generic to all of the Groups of I to XII. The claim is directed to the discovery that the generation of NS-specific activated T-cells, in one way or another, will promote nerve regeneration, confer neuroprotection, and prevent or inhibit neuronal degeneration in the nervous system, whether central or peripheral, thus allowing the amelioration of the effects of

injury or disease. The six techniques of the examiner's Groups I to VI and VII to XII, set forth in subparagraphs (a) to (f) of claim 1, are all techniques for obtaining the same result (i.e., generating NS-specific activated T-cells). This can be done by administering the T-cells themselves, or by administering an antigen or a peptide, or a nucleotide sequence that causes the expression of such an antigen or peptide, in order to activate T-cells thereagainst *in vivo*. All of these are aspects of the same general invention.

MPEP § 803.02, is directed to restriction practice with respect to Markush claims. Claim 1 is effectively a Markush-type claim. This section of the MPEP states that it is improper for the Office to refuse to examine that which applicants regard as their invention unless the subject matter in the claim lacks unity of invention. Here, unity of invention is present because all of the embodiments share the same special technical feature (i.e., causing the production of NS-specific activated T-cells). All of the ingredients which can be used in the method share a common utility and share a substantial structural feature disclosed as being essential to that utility in that all of them, either directly or indirectly, cause NS-specific T-cells to appear *in vivo*.

Similarly, the invention is the same whether used to promote nerve regeneration, or to inhibit neuronal

degeneration. The treatment in accordance with the present invention causes either or both to occur, depending on the injury of disease being treated. The ingredients, process steps, and endpoints are the same regardless of whether regeneration is being promoted or degeneration is being inhibited. The disease or injury will be ameliorated and that is the endpoint. Thus, in all of Groups I to XII, contrary to the examiner's statement, the ingredients are the same as it is always NS-specific T-cells which are being generated, whether they are generated ex vivo and administered directly, or generated in vivo by administering the antigens, or peptides derived therefrom, or by administering nuclectides which then produce the antigens or peptides derived therefrom. The active ingredient is always the NS-specific T-cells and thus the inventions of the single Markush claim are not patentably distinct. Examination of the entire Markush claim in accordance with MPEP §803.02 is therefore in order.

If the examiner considers the Markush claim to be too broad and lacking unity of invention, then it should be rejected on that basis so that recourse can be had to the Board of Patent Appeals and Interferences, rather than to the Director of Patents and Trademarks.

In order to be responsive, applicants hereby elect the invention of Group IX, drawn to a method for preventing or

inhibiting neuronal degeneration by administering a peptide derived from an NS-specific antigen and including claims 1 to 6, 31 to 40, and 41 to 43.

The examiner has also required a number of species elections, although the examiner states that if the species claims are found allowable, then the remainder of the generic claims will be considered. Accordingly, applicant hereby elects the following species:

With respect to paragraph 3, species (a), injury

With respect to paragraph 4, species (c), central nervous system.

With respect to paragraph 5, species (e), spinal cord injury.

With respect to paragraph 6, it is not believed that this is applicable to the elected invention, but to the extent that an election is still required, applicant elects (cc), sensitized to a peptide derived from an NS-specific antigen.

With respect to paragraph 7, species nn, Nogo-A.

With respect to paragraph 8, it is not believed that this species is applicable to the elected invention but to the extent that it may be necessary, applicant hereby provisional elects species tt, Nogo.

With respect to paragraph 9, applicant elects species bbb, subcutaneously.

Thus, it is urged that the examiner's initial examination be directed to a method for preventing or inhibiting neuronal degeneration comprising administering a peptide derived from an NS-specific antigen wherein this peptide is an epitope of Nogo-A, and is administered subcutaneously for ameliorating the effects of injury in the central nervous system, and particularly spinal cord injury. Once this species is found to be allowable, it is urged that all of the species within the scope of presently appearing claim 1, should be examined and allowed in this case. Claims 1, 2, 3, 31, 32, 38, 39 and 41 presently read on the elected species.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.
Attorneys for Applicant(s)

By _____
Roger L. Browdy
Registration No. 25,618

RLB:wlm
Telephone No.: (202) 628-5197
Facsimile No.: (202) 737-3528